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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/912,947	07/25/2001	Bjorn Dahlback	INL-036DV	7730

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EXAMINER
SAUNDERS, DAVID A

ART UNIT	PAPER NUMBER
1644	13

DATE MAILED: 02/04/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.	Applicant(s)
912,947	DAHLBACK
Examiner	**Group Art Unit**
SAUNDERS	1644

—The MAILING DATE of this communication appears on the cover sheet beneath the correspondence address—

P riod for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, such period shall, by default, expire SIX (6) MONTHS from the mailing date of this communication .
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

Status

☑ Responsive to communication(s) filed on 3/6/02.

☐ This action is **FINAL.**

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 1 1; 453 O.G. 213.

Disposition of Claims

☑ Claim(s) 40-42, 44-52 is/are pending in the application.

Of the above claim(s)_____ is/are withdrawn from consideration.

☐ Claim(s)_____ is/are allowed.

☐ Claim(s)_____ is/are rejected.

☐ Claim(s)_____ is/are objected to.

☑ Claim(s) 40-42, 44-52 are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The proposed drawing correction, filed on_____ is ☐ approved ☐ disapproved.

☐ The drawing(s) filed on_____ is/are objected to by the Examiner.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119 (a)-(d)

☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 11 9(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number)_____.

☐ received in this national stage application from the International Bureau (PCT Rule 1 7.2(a)).

*Certified copies not received:_____.

Attachment(s)

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s)._____

☐ Interview Summary, PTO-413

☐ Notice of Reference(s) Cited, PTO-892

☐ Notice of Informal Patent Application, PTO-152

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Other_____

Office Action Summary

The amendment of 3/6/02 has been entered. The claims pending are 40-42 and 44-52.

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 40-42 and 44-52, drawn to determining the presence of or a predisposition to inherited APC resistance via analysis of nucleic acids, classified in class 435, subclass 4.

II. Claims 40, 42, 45, 47 and 49, drawn to determining the presence of or a predisposition to inherited APC resistance via an immunoassay, classified in class 435, subclass 518+.

The inventions are distinct, each from the other because:

Inventions I and II are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions the analysis of nucleic acid samples and the analysis of protein samples via an immunoassay involve use of substantially different reagents and different steps. Furthermore having a reagent for the one (e.g. an antibody specific for an epitope on mutated Factor V) would not suggest or show one how to obtain the reagents for the other (e.g. nucleic acid hybridization probes. The two inventions are thus patentability distinct.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

It is noted that the above stated restriction has Grouped claims 40, 42, 45, 47 and 49 with both Groups I and II. These will be examined only for the elected embodiment.

Independent claims 40 and 47 could encompass methods involving either nucleic acid analysis (Group I) or an immunoassay (Group II). It appears, likewise, that dependent claims 42 and 49 might encompass methods involving either Group. Claim 45 has been included with both Groups because it is unclear which it encompasses (e.g. line 2 refers to detecting "a nucleic acid fragment or abnormal sequence, while line 3 refers to an immunoassay.

It is further noted that the restriction is deemed proper since any potentially interfering applications or patents might be drawn to claims conflicting with only one of Groups I or II.

In the event that Group I is elected the following election of species requirement applies.

This application contains claims directed to the following patentably distinct species of the claimed invention: detection of the mutation via hybridization (e.g. claim 41, 51 and 52) detection of the mutation by linkage to a neutral polymorphism (e.g. claims 42, 49). Detection of the mutation by nucleic acid sequencing (e.g. claims 44, 46 and 50).

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 40, 45, 47 and 48 are generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claims 40, 45, 47 and 48, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David A. Saunders, Ph.D., whose telephone number is (703) 308-

3976. The examiner can normally be reached on Mon.-Thu. from 8:00 a.m. to 5:30 p.m. The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan, can be reached on (703) 308-3973. The fax phone number for the organization where this application or proceeding is assigned is (703) 305-3704.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

D. Saunders:jmr

January 28, 2003

David G Saunders

DAVID SAUNDERS
PRIMARY EXAMINER
ART UNIT ~~182~~ 1644